

Clean Version of Pending Claims


METHOD AND APPARATUS FOR MEASUREMENT OF BLOOD SUBSTITUTES


Applicant: James Sansoondar et al.

Serial No. 09/367,859

Filed September 2, 1999

8. (Twice Amended) A method of determining the concentration of one or more than one analyte contained in a specimen comprising a blood substitute interferent, said method comprising the steps of:

- 
- i) generating a calibration algorithm for said blood substitute interferent;
 - ii) deriving one or more than one linear equation defining a relationship between a measured concentration of said one or more than one analyte and a concentration of said blood substitute interferent using one or more than one sample comprising said one or more than one analyte and said blood substitute interferent;
 - iii) measuring an absorbance or reflectance of radiation of said specimen, wherein the measuring is performed prior to or in the absence of any reaction step that generates a chromophore performed on said specimen;
 - iv) using said calibration algorithm and said absorbance or reflectance measured in step (iii) to predict the concentration of said blood substitute interferent [present] in said specimen;
 - v) measuring an initial concentration of said one or more than one analyte in said specimen; and
 - vi) using a slope from said one or more than one linear equation from step (ii), said concentration from step (iv), and said initial concentration from step (v), to determine a corrected concentration of said one or more than one analyte.



10. (Once Amended) The method of claim 23 wherein said one or more than one analyte is chosen from the group consisting of Na, K, Cl, HCO₃, Ca, Mg, creatinine, urea, total protein, gamma glutamyl transferase (GGT), aspartate amino transferase (AST), lactate

dehydrogenase (LDH), creatine kinase (CK), alkaline phosphatase (ALP) and total bilirubin (Tbili).

11. (Once Amended) The method of claim 8 wherein reflectance is used in step (iii).

12. (Once Amended) The method of claim 8 wherein the radiation is in the range of 474-910 nm.

23. (New) The method of claim 8 wherein absorbance is used in step (iii).

24. (New) A method of determining the presence of true hemolysis, pseudo hemolysis caused by a blood substitute interferent, or both, in a specimen, comprising the steps of:

- i) measuring an absorbance of radiation of said specimen, wherein the measuring is performed prior to or in the absence of any reaction step that generates a chromophore performed on said specimen;
- ii) incorporating said absorbance measured in step (i) into a first calibration algorithm to determine the presence, concentration, or both, of said blood substitute interferent; and
- iii) incorporating said absorbance measured in step (i) into a second calibration algorithm to determine the presence, concentration, or both of Hb liberated from blood cells;

wherein, a positive concentration value of blood substitute interferent, or Hb, is an indicator of pseudo-hemolysis, or hemolysis, respectively.

25. (New) The method of claim 8 wherein said specimen further comprises one or more than one non-blood substitute interferent.

26. (New) The method of claim 8, wherein in the step of deriving (step ii), said one or more than one sample further comprises one, or more than one, non-blood substitute interferent.

27. (New) The method of claim 25, wherein said one or more than one non-blood-substitute interferent is selected from the group consisting of hemoglobin (Hb), bilirubin (BR), biliverdin (BV), turbidity and a mixture thereof.

28. (New) The method of claim 26, wherein said one or more than one non-blood-substitute interferent is selected from the group consisting of hemoglobin (Hb), bilirubin (BR), biliverdin (BV), turbidity and a mixture thereof.

29. (New) The method of claim 24, wherein said specimen further comprises one, or more than one, non-blood substitute interferent.

30. (New) The method of claim 29, wherein said one or more than one non-blood-substitute interferent is selected from the group consisting of intralipid (IL), bilirubin (BR), biliverdin (BV), turbidity and a mixture thereof.